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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,901	09/19/2001	Norman J. Dovichi	45504-019	2915
20277	7590	05/23/2005	EXAMINER	
MCDERMOTT WILL & EMERY LLP 600 13TH STREET, N.W. WASHINGTON, DC 20005-3096			LUDLOW, JAN M	
			ART UNIT	PAPER NUMBER
			1743	
DATE MAILED: 05/23/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,901

Applicant(s)

DOVICH, NORMAN J.

Examiner

Jan M. Ludlow

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-20,22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 7-9,17-20,22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/19/2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1743

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-4, 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/33989 (WO).

WO teaches a first electrophoresis capillary 56, a second electrophoresis capillary 116 and interface 80 with reagent inlet 84 and waste outlet 76. Detectors 52 and 88 are provided and power supplies 60 and 92 are used to perform the electrophoresis. Detectors include fluorescence detectors (p. 13, line 4) and the types of electrophoresis include isoelectric focusing and sieving, and different separation media and conditions are selected to enhance separation (p. 17, lines 20-25). Added

reagents include enzymes and antibodies (p. 20, lines 13-21), which constitute derivatizing agents in that they react with the analytes to form derivative products, such as degradation products and bound complexes. In addition, components can be fluorescently labeled (p. 13-15). WO further teaches a method of introducing fractions from the first channel to the second channel by transferring aliquots a predetermined regular time intervals. In that the first detector is eliminated in this embodiment, it is the examiner's position that all fractions are passed in time sequence. Subsequent aliquots are transferred after the preceding aliquot has traveled far enough into the second channel (p. 20, first paragraph). With respect to "two or more components", Figure 6 shows plural separated components in the second dimension.

WO fails to explicitly teach separately passing the fractions through the second channel.

It would have been obvious to wait until a preceding sample exited the second channel before injecting a subsequent sample if one were willing to forego the time savings of injecting the second sample when the preceding sample was sufficiently far along in the channel not to interfere with the subsequent sample. It would have been obvious to perform sieving electrophoresis as the second form of capillary electrophoresis in order to classify separated components by molecular weight using a technique taught by WO.

4. Claim 5, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO as applied to claims above, and further in view of Moring.

WO fails to teach adding fluorescent label at the interface.

Moring teaches an interface similar to that of WO. Fluorescent label may be added at the interface (see, e.g., abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the label at the interface in WO in order to add the label at an alternative point in the reaction and separation sequence as taught by Moring.

5. Claims 6, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO and Moring as applied to claims above, and further in view of Yeung et al.

WO fails to teach a plurality of interfaces in a manifold.

Yeung et al teaches a system for performing chromatography followed by electrophoresis or other separation. A manifold 26 connects channel 90 to valve 22, which is connected to a syringe pump 19, and a variety of reservoirs via ports 53-57 (col. 11, lines 41-59). The manifold is also coupled to interfaces 32 which couple the chromatographic columns 14 to the electrophoresis capillaries 33 and outlet channels coupled to manifold 31. Laser induced fluorescence is used to detect separated components (e.g., col. 21, line 17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a manifold as taught by Yeung in the apparatus and method of WO in order to perform plural simultaneous separations with reagent addition at the interface as taught by Yeung. The manifold of Yeung is unitary in that all its parts are joined together in a unit. It would have further been obvious to use laser induced fluorescence as the fluorescence detection in WO in order to provide an art recognized alternative detection system as taught by Yeung.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Khan et al is related to WO 95/33989.

7. Applicant's arguments filed October 5, 2004 with respect to claims 1, 3-6, 10-16 have been considered but are not persuasive.

8. Initially, the examiner notes that while support for the amendments is not found explicitly in the text of the specification, the combinations of two dimensions of separation disclosed include pairs of different separation means. Further, Figure 3 shows at least one fraction having two or more components.

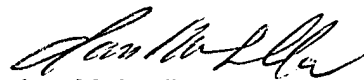
9. Applicant's arguments with respect to WO using only "selected" fractions are not persuasive because the examiner has relied upon the teaching on page 20, paragraph 1 in which aliquots are "selected" based purely on the time of elution, and no passage of intermediate aliquots to waste is described. Note that WO teaches that this method requires many more transfer steps, which reinforces the examiner's interpretation that all aliquots are sampled. Further, since the first detector is eliminated, there is no basis on which to "select" a fraction, so it would have been obvious to pass all the fractions. The examiner regrets that applicant finds it "hard to fully comprehend" page 20, paragraph 1, but the examiner has given the passage a reasonable interpretation, including the common meaning of the term "aliquot". Applicant argues that the invention of WO has as an "important aspect" the ability to transfer a selected band, but it is the examiner's position that this statement refers to the improved process with the first detector in which a band can be selected, not the alternative time sampling in which there is no teaching of how to select a band, given that the first detector is eliminated.

10. With respect to "two or more components", Figure 6 shows plural separated components in the second dimension.
11. Applicant argues that WO does not teach two different separation modes, but WO does teach different separation means, see, e.g., p. 17, lines 28-31.
12. Applicant argues that WO separates components, subjecting them to reaction, and then carrying out a second separation in the second capillary. The examiner notes that this is no different from the instant invention in which the reaction is a labeling reaction. For comparison, see, e.g., p. 24, lines 10-20 in which labeled binding reagents are reacted with the components.
13. Applicant argues that only electrophoresis is suitable for the instant method of starting and stopping the first dimension (which is not claimed), but the instant rejection is based on electrophoresis. Further, p. 20, paragraph 1 of WO teaches starting and stopping the first electrophoretic dimension.
14. Applicant argues that the specific combination of isoelectric focusing and sieving electrophoresis is not taught by WO, but both methods are taught form within a finite grouping, thus making obvious any combination thereof. Further, applicant admits that this combination is "classic" or conventional (p. 12, lines 11-21).
15. Applicant argues that there is no basis for application of a fluorescent label in WO, but WO teaches labeling (e.g., p. 24, lines 10-20) as well as fluorescent measurement (p. 7, line 18).
16. With respect to Yeung, applicant argues that the manifold is not unitary, but the manifold of Yeung is unitary in that all its parts are joined together in a unit.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jan M. Ludlow
Primary Examiner
Art Unit 1743

Jml
May 16, 2005